9 September 2011
EMA/646917/2011

Release notes

EudraCT Version: 8.1.1

Goal: Release 8.1 Iteration 2

Release Date: 12/09/11

Environment: Production (Public)

Release Contents:

This is the production release of the second iteration of EudraCT 8.1. It includes the following main functional changes:

- Further user interface improvements to enhance the design of data entry forms by eliminating manual data entry where information can be auto-populated and by hiding questions where not applicable as a result of answers in other parts of the form.

- To make viewing of a detailed CTA easier for users to read the view has been changed so that, for radio button fields, only the selected answer is shown (rather than displaying all radio button options even if they are unselected).

- Advisory text in grey now appears in other languages free text fields for EEA and 3rd Country forms. The text will advise: "Please enter information in other language that is applicable".

- The EEA PDF no longer shows Submission Reason section

The release also includes some further changes to address identified defects in the main application and to address comments raised during user acceptance of 8.1 iteration 1.

The impacted use cases / testable functionalities are listed below:

Functionality / Use Case	Comments
BUC05 Fill in CT Application Form	Enhanced form logic changes, expand / collapse and other UI changes
BUC05 Fill in CT Application Form	Further enhancements to form logic, help text changes and other UI improvements and defect fixes.

Functionality / Use Case	Comments
BUC07 Download and Print PDF	Removal of unselected radio buttons in PDF output to make PDF easier to read. Note on PDF form to advise that D.3.6.1 and D.3.6.2 are legacy fields and to remove the data. Removal of Submission Reason from PDF form.
BUC55 Validate 3rd country CT Form	Validation rule update to 3rd Country form.
BUC58 Validate Clinical Trial Application	Validation rule update to EEA form.

Below is the complete list of new features including improvements and help text changes, defect fixes identified and addressed in this release and technical improvements included in this release.

Issue Type	Priority	Key	Summary
New Feature	Critical	ECT-3089	Text in Grey to appear in other languages free text fields for EEA & 3rd Country. The text will advise: "Please enter information in other language that is applicable"
New Feature	Major	ECT-3071	Label change. E.8.7 Trial having a data monitoring committee Label changes to E.8.7 Trial having an independent data monitoring committee. This for both EEA & 3rd country screens.
New Feature	Major	ECT-3077	BUC05 - Enhanced Form Logic / D.5
New Feature	Major	ECT-3078	BUC05 - Enhanced Form Logic / D.6
New Feature	Major	ECT-3079	BUC05 - Enhanced Form Logic / D.7
New Feature	Major	ECT-3080	BUC05 - Enhanced Form Logic / D.8
New Feature	Major	ECT-3087	BUC05 - Enhanced Form Logic / FEAT 21.8.32 - G.2.5.4 Country
New Feature	Major	ECT-3088	BUC05 - Enhanced Form Logic / FEAT 21.8.33 - H.2.2.4 Country
New Feature	Major	ECT-3092	BUC05 - Enhanced Form Logic / FEAT 6.2.1.55 E.8.2.4
New Feature	Major	ECT-3125	New tag to display help text for F.4.2 For a multinational trial
Improvement	Major	ECT-3159	Label to be added to blue bar panel header for fields D.2.3, D.2.4, D.2.5, D.2.6 to make these fields easier to locate.

Change Request	Major	ECT-3165	C.2.1 And C.2.2 Sponsor Information/Legal Representative - Enhanced Form Logic - Automatic population of sponsor information if the sponsor is also an applicant. Similarly, automatic population of legal representative information if the legal representative is also an applicant.
Defect	Major	ECT-3175	D.3.6.2 Maximum dose allowed - FEAT6.2.4 Validation rule relaxed for field D.3.6.2 as this is read only legacy data (non mandatory).
Defect	Major	ECT-3178	Address defect from UAT of 8.1 iteration 1 - Help tool tips disappearing when error is encountered once a value is selected from C.1, C.2 drop down menu
Defect	Major	ECT-3183	Address UAT comment from 8.1 iteration 1 - Add a green circle to B.3.1 and B.3.2 Status of the Sponsor. This field is public on the EU CTR for all trials
Improvement	Major	ECT-3200	A.3.2 Name or abbreviated title of the trial where available - change to UI to make field longer
Improvement	Major	ECT-3204	Revise the error message that currently appears on A.8 EMEA Decision Number to read as follows

- A.8 EMA Decision number of Paediatric Investigation Plan: the value entered should have the format: P/xxx/yyyy where xxx is 1, 2 or 3 digits and yyyy represents years. The year value must be greater than 1999 and no more than 2099. |
Improvement	Major	ECT-3206	Revise error message on incorrect entry of field C.1.5.1 to make it clearer to the user.
Change Request	Major	ECT-3212	Change EEA BA Template to hide Submission Reason section when creating PDF
Defect	Major	ECT-3222	D.3.11.3.2 Change "Medical Product" to "Medicinal Product"
Change Request	Major	ECT-3234	Legacy fields D.3.6.1 and D.3.6.2 (which were made read-only in 8.1 iteration 1) are no longer displayed in the CTA PDF output.
Defect	Major	ECT-3225	On panel section labels "D.2.3", "D.2.4" and "D.2.6" removed for 3rd Country Clinical Trials (as not applicable)
Defect	Major	ECT-3221	Defect fixed for BUC58: FEAT6.2.1.52 where rule was triggered when D.7.4.1 = No. Now, the rule is only triggered if D.7.4.1 is Yes and D.7.4.1.1 is "Not Answered".
Improvement	Major	ECT-3235	Change to CTA output to sort G.1, G.2 investigator entries by their role

Defect	Major	ECT-3227	3rd Country PDF - incorrectly shows 'No' to IMP "Comparator" when it should actually be Yes
Change Request	Major	ECT-3236	Update Help Text - D.3.6.1 First Dose for first in human clinical trial
Change Request	Major	ECT-3248	BI templates (Spanish translations) updated to be in line with cumulative changes that have been made to the English template.
Defect	Minor	ECT-3161	If C.1.5.1.1 completed incorrectly then user is taken to CTA summary menu and error displayed rather than error being displayed in section C so fields can be amended (3rd Country only)
Improvement	Minor	ECT-2889	Rename section C.1 of 3rd Country trial and Updates to the help text
Defect	Minor	ECT-2924	Fix to minor discrepancy in text displayed on the UI and PDF output for 3rd Country screens (fields E.8.3 and E.8.4)
Defect	Minor	ECT-3011	Support Call 110830 - Middle name in G.4 Networks to be involved in the trial should be optional.
Defect	Minor	ECT-3151	Fix to comment raised in UAT v8.1 iteration 1 - change the EVMPD URL in the help text for D.2.1.1.1.1
Improvement	Minor	ECT-3155	Fix to comment raised in UAT v8.1 iteration 1 - Direct users to the top of the screen so they can more easily find error message when at the bottom of the screen
Improvement	Minor	ECT-3160	Improvement to page help in Section C.
Defect	Minor	ECT-3170	Fix to defect where in section A.3 "Please enter information in English.." disappears from the rest of the fields in that section when more than max characters entered in first free text field
Defect	Minor	ECT-3176	Fix to defect where, when more than the max allowed is entered in any English and multilingual fields, then text entered in other English field appears in Italics
Defect	Minor	ECT-3181	Fix to comment raised in UAT v8.1 iteration 1 - Field name and number should be included in the error message when multilingual text field is filled in but no language selected or vice versa
Improvement	Minor	ECT-3198	EudraCT Number - Revise error message so clearer when user enters a EudraCT number which is in correct format but does not exist.
Defect	Minor	ECT-3210	3rd Country BI Template - Font size of Trial Identification corrected to be the same as the rest of the section headers

Defect	Minor	ECT-3245	In validation report text labels for sections "D8" and "D9" corrected to add ".", i.e. "D.8" and "D.9".
Defect	Minor	ECT-3182	Fix to UAT comment: Sponsors Protocol Code Number on Trial Identification section accepts spaces
Defect	Minor	ECT-3250	Change language drop down list in the CTA form to be in alphabetical order
Defect	Minor	ECT-3249	Email address entered in C.1.5.1.1 is cleared out if value selected from drop down menu in C.1.1, C.1.2, C.1.3
Defect	Minor	ECT-3179	Help icon text for A.2 EudraCT Number has incorrect reference to section A.7 as resubmission (corrected to A.6).
Defect	Minor	ECT-3226	Correction to minor formatting issue in C1 header of PDF.
Defect	Minor	ECT-3252	Correction to URL extending out of the help text window when user hovers over MedDRA information in section E.1.2.
Defect	Minor	ECT-3223	Removal of non-printable character in help text for Section C.

Additional information
None.

Installation steps deviating from the deployment guide
None.